

### **REMARKS/ARGUMENTS**

The present amendment is in response to the Office Action mailed March 21, 2003, in which Claims 1 through 10 and 12 through 18 were rejected. Applicants have thoroughly reviewed the outstanding Office Action including the Examiner's remarks and the reference cited therein. The following remarks are believed to be fully responsive to the Office Action and, when coupled with the amendments made herein, are believed to render all claims at issue patentably distinguishable over the cited references.

Claims 1, 15 and 16 are amended herein. Claim 13 is cancelled. No new claim is added. Accordingly, Claims 1 through 10, 12 and 14 through 18 remain pending.

All the changes are made for clarification and are based on the application and drawings as originally filed. It is respectfully submitted that no new matter is added.

Applicants respectfully request reconsideration in light of the above amendments and the following remarks.

### **CLAIM REJECTIONS – 35 U.S.C. SECTION 103(a)**

With respect to pages 2 and 3 of the Office Action mailed March 21, 2003, in which the Examiner rejected Claims 1 through 10 and 12 through 18 as being unpatentable over EP 148 600 to Thomas *et al.* in view of Satoh *et al.* and

further in view of Chigurapati *et al.* or Olsen

Applicants respectfully traverse this rejection.

The entire process as presently claimed is arranged in such a way that the final product obtained by the above process of the present invention would have 11% nitrogen, 20 – 23 trypsin inhibitor units/mg protein, 95 – 98% nitrogen solubility index, 2 – 2.2% bitterness recognition threshold and 35 – 45% degree of hydrolysis. The cream colored product further has no detectable lipooxygenase or urease activities and has a similar amino acid make up as the starting material. The process of the present invention has been formulated with these specific requirements in mind. Applicants respectfully observe that none of the documents cited by the Examiner, whether taken alone or in combination, teaches a process for preparing protein hydrolysate having the aforesaid characteristics.

More particularly:

EP 148 600 relates to the preparation of hydrolyzed protein from protein isolate. The solubility profile would depend on the net charge distribution and size of the protein and protein isolate, which is soluble in water but is not soluble at pH 4.5. Similarly, any pretreatment such as jet cooking or other preparatory dynamics as done by EP 148 600 changes the conformation of the protein completely and, quite naturally, changes the properties of the substrate. The proteins would thus become more susceptible to cleavage by proteolytic

enzymes compared to the present invention. Further, heating of the proteins could also result in a change in the nutritional profile such as in the amino acid content. In the current invention, the amino acid profile of the product is the same as the starting material.

The cleavage of protein by papain would depend on the conformation of the protein which determines the extent of exposure of the peptide bond. The exposure of the peptide bond for cleavage by any proteolytic enzyme is dependent on:

- a) Conformation of the protein; and
- b) Charge distribution on the surface of the protein.

Novelty and non-obviousness of the process is dependent upon the selection of the right kind of pH, temperature, enzyme-to-substrate ratio, and conformation of the substrate to give the final desired product. The process parameters that have been used ensure the desired conformation of the protein and the desired charge distribution on the surface of the protein. No other combination of steps or the type of process would result in the product described in the process.

The other primary reference, Thomas *et al.*, teaches the preparation of soy protein concentrate using carbohydrate splitting enzymes like pectinases, phytase and a nuclease. These enzymes are different from proteases and, in fact, do not split the protein component at all. Thus, the soy protein remains

intact. In the present invention, the soy protein is degraded to smaller components (peptides) and the degree of hydrolysis is 35 – 45%.

Chigurapathy *et al* claim a method for producing a savory flavor base. The process involves fermentation. Fermentation relates to a number of changes brought about to the substrate including changes to the carbohydrate, fat and protein component. The present invention only brings about changes in the protein component of the substrate. This is done enzymatically.

Finally, Olsen teaches a method of producing an egg white substitute material from soy protein. More specifically, Olsen teaches enzymatic hydrolysis, however, the described method results in a degree of hydrolysis of only 6% which teaches away from the invention as presently claimed.

Reconsideration and withdrawal of the rejections under 35 U.S.C. Section 103(a) are respectfully requested.

#### **NEW CLAIM 21**

Applicants submit new Claim 21 which is generally based on Claim 1 as presently amended but which also includes limitations directed to ratios and temperatures. Applicants respectfully submit that no new subject matter is presented as support for these limitations may be found in the examples as originally presented (Examples 1 through 4, pages 10 and 11).

### **ENTRY OF AMENDMENT AFTER FINAL**

It is respectfully submitted that the present amendment should be entered in accordance with the provisions of 37 C.F.R. Section 1.116 on the grounds that: (1) The claims as now presented are in better form for appeal purposes, if necessary; (2) no new issues have been raised; (3) and, moreover, the present amendment is believed to place the application in condition for allowance.

### **CONCLUSION**

In light of the above amendments and remarks, Applicants respectfully submit that all pending Claims 1 through 10, 12 and 14 through 18 as currently presented are in condition for allowance. If, for any reason, the Examiner disagrees, please call the undersigned attorney at 248-433-7552 in an effort to resolve any matter still outstanding *before* issuing another action. The undersigned attorney is confident that any issue which might remain can readily be worked out by telephone.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'T. Moga', with a long horizontal flourish extending to the right.

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